THE UNIVERSITY OF ARIZONA Research & Partnerships

Investigational New Drugs (IND)

IND Requirements

Generally, any investigational drug study must follow the IND requirements under 21 CFR part 312 if:

- The research involves a drug as that term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(g)(1));
- The research is a clinical investigation as defined in the IND regulations (21 CFR 312.3);
- The clinical investigation is not otherwise exempt from the IND requirements in part 312;

If a study involves a drug under these circumstances, the *Appendix for Drugs* is required along with the investigator brochure, U.S. Food & Drug Administration (FDA) documentation of approval, and any additional information the Institutional Review Board (IRB) may need to make their determinations regarding use of the drug. If an IND is required by the IRB, the IND goes into effect 30 days after the FDA receives the IND unless the sponsor receives earlier notice from the FDA.

A clinical investigation involving use of a placebo is exempt from the requirements of this part if the investigation does not otherwise require submission of an IND.

Marketed Drugs

Whether an IND is required for a clinical study of a marketed drug depends primarily upon the purpose of the study and the degree of risk associated with the use of the drug. An IND will be required for a clinical investigation of a marketed drug unless all the exemption criteria in §312.2(b) are met:

- The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
- If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product;
- The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and
- The study is not being conducted as a means to promote or commercialize the product.

Bioavailability or Bioequivalence Studies

An IND is not required for bioavailability or bioequivalence studies if the following criteria are met:

- The drug product does not contain a new chemical entity (21 CFR 314.108), is not radioactively labeled, and is not cytotoxic;
- The dose (single dose or total daily dose) does not exceed the dose specified in the labeling of the approved version of the drug product;
- The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR part 56) and with the requirements for informed consent (21 CFR part 50);
- The sponsor meets the requirements for retention of test article samples (21 CFR 320.31(d)(1)) and safety reporting (21 CFR 320.31(d)(3));

Dietary Supplements

An IND may be required for studies involving a dietary supplement if the clinical investigation is intended to evaluate the supplement's ability to diagnose, cure, mitigate, treat, or prevent a disease. A dietary supplement will not be considered a drug and is not subject to the IND regulations if the intended use for which it is marketed is only to affect the structure or any function of the body.

Sponsor's Role

The sponsor or sponsor-investigator is responsible for determining whether an IND is required. The FDA requests the sponsor contact the appropriate review division within the FDA to determine whether the IND regulations apply if the sponsor has any uncertainty if an IND is required. The guidance provides detailed information how to contact the FDA and the process that will be followed for inquiries.

Holder of the IND

If the University of Arizona is the holder of the IND, there is a potential conflict of interest. An outside IRB my need to review the protocol to avoid any potential conflicts. Contact the Office for Responsible Outside Interests for more information: COI@arizona.edu.

Resources

- Human Subjects Protection Program IND Resources: https://research.arizona.edu/compliance/human-subjects-protection-program/resources-investigators/investigational-new-drug-ind
- FDA Guidance: Investigational New Drug Applications (INDs) – Determining Whether Human Research Studies Can Be Conducted Without an IND